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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,206	06/26/2003	Daniel J. Potter	11536US.00	7328
33486	7590	02/27/2006	EXAMINER	
HEIMBECHER & ASSOC., LLC. 6125 SALVIA LANE ARVADA, CO 80403			JACKSON, GARY	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/609,206

Applicant(s)

POTTER ET AL.

Examiner

Gary Jackson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

*Gary Jackson*

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/11/04; 7/07/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is responsive to applicant's amendment filed May 26, 2006. The argument is not deemed to be persuasive to overcome the rejection set forth in the office action mailed April 6, 2005. Therefore the action is repeated herein as in the last Official Action.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller, Jr. 4,938,220 in view of Norlander et al. 6,562,049. Regarding claims 1,9 and 17, Mueller discloses a sheath 19 having at distal end a radiopaque marker 10 including edges to allow for securing it to the sheath member. Mueller lacks teaching of the well-known splittable sheath having score-lines. However, the patent to Norlander discloses as shown in figures 6-10,12 the sheath score lines 46 and further disclose that radiopaque maybe incorporated into the splittable sheath or made of a separate band member. (See column 10, line 63 – column 11, line 4.) It would have been obvious to one having an ordinary skill in the art at the time the invention was made to modify Mueller by adding the sheath score lines in view of Norlander so that the sheath can be split and removed from the patient. In the alternative, it would have been obvious to modify Norlander to include the split ring of Mueller so as readily remove the splittable sheath member.

Regarding claims 2-8 and 10-12, Norlander discloses the first and second sheath score lines 46, and Mueller discloses the first and second edges or score lines 13.

Regarding claims 13-16 and 20, the exact shape of the notch and the material of the radiopaque marker would have been an obvious matter of design choice.

Regarding claims 18 and 19, note figures 1 and 2 of Mueller's reference.

### ***Response to Arguments***

Applicant's arguments filed May 6, 2005 have been fully considered but they are not persuasive. Splittable marker at the distal end of a splittable sheath is known in the art. It is further well known in the art to include the radiopaque marker material embedded in the distal end of a splittable sheath of make the marker of separate ring member. US Patents 6,277,108 ('108) and 6,159,198 ('198) (cited to show the state of the art) teach such concepts. The patent '108 teach the well-known concept of a splittable marker at the distal end of a splittable sheath. See column 4, lines 25-58. Likewise, patent '198 teach the same concept at column 3, lines 22-27.

For these reasons, it would have been within the purview of one having ordinary skill in the art to modify Mueller of Norlander to teach the concept of a splittable radiopaque marker at the distal end of a splittable sheath.

Further, since it is known to embed marker material at the distal end of a splittable sheath having multi tear lines; certainly it would have been obvious to form the marker with multiple score-lines for easier removal. See figure six of patent '108.

For these reasons, the examiner believes the action is proper and therefore made final.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

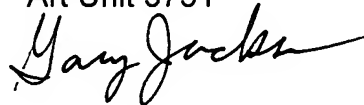
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary Jackson whose telephone number is (571) 272-4697. The examiner can normally be reached on Mon.-Thurs. 7:30 am to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Jackson  
Primary Examiner  
Art Unit 3731

A handwritten signature in black ink that reads "Gary Jackson". The signature is written in a cursive style with a long horizontal flourish extending to the right.

gj  
February 15, 2006